UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IMS HEALTH INCORPORATED, a Delaware corporation and VERISPAN, LLC, a Delaware limited liability company, Plaintiffs, v. KELLY A. AYOTTE, as Attorney General of the State of New Hampshire, Defendant.	06-CV-280-PB

BRIEF OF *AMICUS CURIAE* WOLTERS KLUWER HEALTH, INC.
IN SUPPORT OF PLAINTIFFS' POSITION

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STATEMENT OF INTEREST OF *AMICUS CURIAE* WOLTERS KLUWER HEALTH, INC.

Wolters Kluwer is a leading multinational publishing and information services company active in many markets, including the sale of health care products. One division, Wolters Kluwer Health, Inc. ("Wolters Kluwer Health"), a wholly owned subsidiary of Wolters Kluwer U.S. Corporation, is a primary supplier of information to professionals and students in the fields of medicine, nursing, allied health, and pharmacy, as well as to entities in the pharmaceutical industry. It produces textbooks, reference products, journals, and other informational materials that professionals employ in the knowledge-intensive, rapidly changing practice of medicine. Wolters Kluwer Health, through its wholly owned subsidiary, Source Healthcare Analytics, Inc., sells a variety of information products that use "prescriber-identified prescription data," *i.e.*, records that match the details of individual prescriptions to the prescribing professional. To create these information products, Wolters Kluwer Health purchases prescriber-identified data from a pharmacy or other originating entity, then aggregates, analyzes, and packages it for client use.

Wolters Kluwer Health's clients use the data in a broad range of activities. For example, pharmaceutical manufacturers use it to identify doctors who may be interested in their products and who may have patients who would be suitable participants in clinical trials of promising new drugs. Retail pharmacies purchase the aggregated data, which gives a clear picture of the prescribing practices of doctors whose prescriptions they are filling, and use it as a guide in discharging their own professional obligations. Among other things, pharmacies use the data to detect abusive prescribing practices and to identify doctors who appear not to be giving appropriate consideration to more cost-effective generic drug alternatives. A number of governmental agencies, including the FDA, use the data in discharging their regulatory and law

enforcement responsibilities. Products like Wolters Kluwer Health's can help governmental agencies direct drug safety alert letters toward doctors whose prescribing practices make them relevant, and enforce civil and criminal laws against abusive prescribing practices. In addition, a variety of individuals and organizations use the data in research concerning drug usage, interactions, effectiveness, and costs.

The statute at issue in this case, New Hampshire's Prescription Restraint Law ("the Law"), threatens to prevent Wolters Kluwer Health from purchasing, aggregating, and selling prescriber-identified information. In addition to harming Wolters Kluwer Health's sales and profits, the Law will hinder the dissemination of truthful information the availability of which serves the public interest in a variety of ways.

INTRODUCTION

The Law. The Prescription Restraint Law, 2006 N.H. Laws 328 (codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12, IV), came into force on June 30, 2006. The Law, which is the first statute of its kind in the United States, makes unlawful and subjects to civil and criminal penalties the sale, "license[], transfer[], [or] use[]", for "any commercial purpose," of prescriber-identified prescription drug information. *Id.* § 318-B:12, IV. A "[c]ommercial purpose includes, but is not limited to . . . any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force." *Id.* The Law expressly applies to key players in the health care industry, including any "pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity." *Id.* The Law also includes two separate but overlapping lists of exceptions, one enumerating "limited purposes"

for which prescriber-identified data may be used or disseminated,[1] and one listing activities the statute does not prohibit.[2]

The Law's exceptions raise many questions about the statute's reach. Because neither "commercial purpose" nor any of the exceptions are defined with clarity, the institutions to which the law appears to apply, including the New Hampshire pharmacies that supply the data, cannot tell whether their use or dissemination of prescriber-identified data will run afoul of the statute. This is not a minor concern, since under the Law, violations are punishable by a fine of up to $10,000 *each*. *See id*. § 358-A-4.

The Legal Challenge. On July 28, 2006, IMS Health Incorporated and Verispan, LLC, filed the instant suit alleging that the Prescription Restraint Law's ban on the use and dissemination of prescriber-identified data violates the First and Fourteenth Amendments and the Commerce Clause of the United States Constitution. IMS and Verispan seek to enjoin the Law's enforcement. Wolters Kluwer Health files this brief *amicus curiae* urging the Court to invalidate the Prescription Restraint Law's restrictions on the use of prescriber-identified data and advancing two principal arguments: (1) the Law may well forbid, and, in any event, will have the practical consequence of foreclosing, many valuable uses of truthful information that serve the

[1] The authorized "limited purposes" are "pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or agent of either; health care research; or as otherwise required by law." N.H. Rev. Stat. Ann. § 318-B:12, IV.

[2] "Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials." *Id.*

public interest, and (2) narrower means are available to accomplish the Law's goal of protecting physician privacy.

ARGUMENT

The Prescription Restraint Law Violates The First Amendment By Restraining The Dissemination Of Prescription Drug Information That Serves Many Important Purposes

The Prescription Restraint Law violates fundamental First Amendment rights by foreclosing the free exchange of truthful information among individuals and entities in the health care community. The result is the same whether the statute is viewed as a content-based restriction on speech subject to strict scrutiny or as a regulation of commercial speech subject to intermediate scrutiny. By virtue of its broad and vague provisions, the statute effectively renders unavailable for any purpose an important category of information that is valuable to researchers, physicians, patients, and the entire health care community.

Under the First Amendment, content-based restrictions on speech are "presumptively invalid" and subject to strict scrutiny, *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992), as are content-neutral restrictions that penalize the dissemination of "lawfully obtain[ed] truthful information about a matter of public significance," *Smith v. Daily Mail Publ'g Co.*, 443 U.S. 97, 103 (1979). These kinds of restrictions will be upheld only if they serve a compelling governmental interest and use the least restrictive means to do so; if a less restrictive means exists, the State *must* employ it. *See, e.g., Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997).

Historically, commercial speech—speech that does "no more than propose a commercial transaction," *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council*, 425 U.S. 748, 762 (1976) (citations omitted)—has received a slightly lower level of protection under the First Amendment. A State may restrict commercial speech only if the speech is illegal, fraudulent, or misleading; or

if the law directly advances a substantial government interest by means "not more extensive than is necessary." *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

The Prescription Restraint Law is subject to strict scrutiny whether the Court regards it as content-based or content-neutral because it penalizes the dissemination of truthful information concerning matters of considerable public significance. In particular, the Law threatens to cut off an important source of information for researchers, governmental bodies, pharmacies, physicians, and other health care providers and thereby frustrate their efforts to advance the public interest in top-quality health care. And, in any event, the Law cannot survive intermediate scrutiny under the commercial speech doctrine, because it is "more extensive than is necessary" to advance the objective of protecting physician privacy. Earlier this year, the American Medical Association instituted a narrower, voluntary program that honors the requests of physicians who wish to keep their prescribing practices private from pharmaceutical sales personnel without curtailing large amounts of valuable speech, including speech concerning the prescribing practices of physicians who express no objection.[3] Other mechanisms that do not impinge upon free speech also exist to advance the interest. Since the Prescription Restraint Law strikes at the heart of the First Amendment's protection of speech, this Court should invalidate the Law's restrictions on the use of prescriber-identified data.

[3] Although legislators who supported the Prescription Restraint Law claim that it protects the "privacy" rights of physicians, there is no historical, legal, or practical basis to classify the information at issue as "private" in any meaningful sense. The information resides with third-party businesses such as pharmacies and other similar entities; the statute specifically allows transfer of the information to numerous other entities such as insurers and health care researchers; the statute specifically allows extensive use of the information for non-commercial and some commercial purposes; and the information itself reveals nothing about the "private" life of the prescriber—rather, it shows the choices of a closely regulated health care professional concerning pharmaceutical products without revealing anything about the professional's patient.

A. The Prescription Restraint Law's Breadth And Vagueness Will Lead To The Suppression Of A Substantial Amount of Critical Constitutionally Protected Speech

The Prescription Restraint Law is a great impediment to the free flow of information that is—in the words of the American Medical Association—"critical to improving the quality, safety, and efficacy of pharmaceutical prescribing through evidence-based medical research."[4] The Law's prohibition on licensing, transferring, using, or selling prescriber-identified information for "any commercial purpose" will frustrate activities ranging from the benign to the highly beneficial. The affected entities and activities include:

Researchers. Researchers developing new drugs use prescriber-identified data to locate physicians who may be able to help identify potential participants for clinical trials. These trials benefit both the patient-participant and the researcher. Researchers also use prescriber-identified information—and sometimes contact the treating doctors—when studying drug responses and drug interactions. While the statute excludes "health care research" from the list of proscribed commercial purposes, the exclusion's breadth is unclear. Given that the statute's core purpose appears to be restricting the promotion of pharmaceuticals, the research exception is too vague to provide any meaningful comfort to researchers engaged in clinical trials on behalf of pharmaceutical companies.

Retail Pharmacies. Wolters Kluwer Health sells retail pharmacies a number of products that include the prescribing activities of doctors in their areas, which the pharmacies use for a variety of purposes. For example, when retail pharmacies begin to stock a drug that has some notable advantage over a drug a physician currently prescribes, or has been shown to interact

[4] Am. Med. Ass'n, *AMA's Position Regarding State Proposals to Restrict Disclosure of Physician Prescribing Data* 1 (2006), http://www.ama-assn.org/ama1/pub/upload/mm/432/rxnostatepaperposoct.pdf.

with a drug the physician commonly prescribes, the pharmacy may alert the physician and give him the opportunity to use a different drug. Such communications are highly beneficial to patients and health care providers, and offer doctors the opportunity to alter their practices to prescribe specific drugs that may be more appropriate under the circumstances. Pharmacies also frequently contact physicians to bring to their attention the availability of cheaper, generic alternatives to the drugs they prescribe. Such valuable communications appear to be illegal under the Law and therefore the Law works against, rather than advances, the goal of reducing prescription drug costs. In addition, pharmacists use such data to discharge their ethical obligation to be on the lookout for abusive drug prescribing practices by doctors whose prescriptions they are filling.

Pharmaceutical Companies. Pharmaceutical companies use prescriber-identified data to locate physicians who would benefit from free samples of their drugs—samples that physicians can then distribute to their patients free of charge. These companies also perform internal reviews of the effectiveness of their sales forces and marketing campaigns to ensure that millions of dollars in sample drugs and advertising are not wasted on physicians who have no use for them. These efforts not only ensure that information reaches the most interested listeners but also reduce marketing costs for pharmaceutical companies, which may lead in turn to reduced drug costs.

Health Insurance Companies. In one of many efforts to cut health care costs, the Blue Cross Blue Shield Association has assembled the nation's largest private database of health care information. The database "compiles the maladies, diagnoses, surgeries, drug prescriptions and other treatment details for 79 million people nationwide, minus patient names to ensure privacy." Julie Forster, *Blues Database Tracks How We Use Health System*, St. Paul Pioneer Press, Aug. 5,

2006, at A1.[5] The company plans to use the database "to find better and cheaper medical treatments," *id.*—a goal that necessarily will involve efforts to influence prescribing behavior. Initiatives like this one, which seek to advance the statutory goal of cutting costs, are directly threatened by New Hampshire's Prescription Restraint Law.

Governmental Agencies. Governmental agencies, such as the Food and Drug Administration and the United States Department of Justice, use prescriber-identified information generated by health information organization like Wolters Kluwer Health for a host of purposes, including detecting and prosecuting abusive prescription drug practices.

These are just a few examples of the uses of prescriber-identified prescription information that stand to be disrupted, if not entirely foreclosed, by the Prescription Restraint Law. The Law, with its apparent broad prohibition of speech and numerous undefined exceptions, most certainly will chill the exchange of constitutionally protected speech in at least two ways. *First*, the pharmacies that serve as the principal source of raw prescriber-identified data could decide to stop making it available to health information organizations like Wolters Kluwer Health. This is not a distant possibility—certain pharmacy organizations operating within New Hampshire have already indicated to Wolters Kluwer Health that they intend to withhold either all prescription data, or at least the identities of prescribers. *Second*, many other individuals and institutions in the health care industry are likely to err on the side of caution and refrain from highly beneficial activities out of fear that they will risk legal penalties by disseminating or using prescriber-identified data.

[5] *See also* KaiserNetwork.org, Blue Cross Blue Shield to Create Database of Member Claims, Aug. 7, 2006, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID =38977.

In short, the Law targets and could largely if not entirely eliminate communication about individual doctor prescribing practices—communication that serves important public purposes. As such, it should be subject to strict scrutiny, which it plainly cannot survive.

B. This Wholesale Suppression Of Important Speech Is Not Remotely Justified By The Desire To Protect Physician Privacy, Which Interest Is The Focus Of A Voluntary Program Now Being Implemented By The American Medical Association

Even if the Court decides the Law regulates commercial speech, it still cannot survive intermediate scrutiny because it is far "more extensive than is necessary." *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566. In this case, there is no denying that a narrower law could protect the state interest said to be at stake, because the American Medical Association ("AMA") has already put into place a narrower alternative that allows individual physicians to have their own prescription information withheld from sales personnel, without unduly limiting the dissemination and use of other valuable speech.[6]

The Prescribing Data Restriction Program, or "PDRP," is the AMA's response to complaints it has received over the years from physicians who did not want pharmaceutical sales representatives to have access to their prescription practices. The PDRP, which took effect on July 1, 2006, allows participating health care professionals to protect their prescriber-identified information from being disclosed to sales representatives.

The PDRP is entirely voluntary on the part of physicians. Prescribers choosing to participate in the program may use the AMA website to request that their identities be withheld

[6] The Law's sponsors appear to have had two purposes in mind: (1) protecting physicians who object to dissemination of information concerning their prescribing practices and (2) reducing prescription drug costs. Wolters Kluwer Health agrees with Plaintiffs that the Law fails to advance and even appears to frustrate the second purpose, and notes that it is at best counter-intuitive to suppose that any suppression of true information will have the effect of reducing costs in a market-based economy. The argument in this part of the brief focuses, however, on the Law's overbreadth as a means of protecting physician "privacy."

from pharmaceutical company sales representatives. If a prescriber later changes his mind, he need only contact the AMA via e-mail or telephone, and the AMA will cease to require his identity to be withheld. The PDRP is available to AMA members and non-members alike at no charge.

The AMA is able to make this program work effectively because it controls an important source of information called the "Masterfile." The Masterfile is a list containing detailed information about all physicians in the United States. The AMA licenses use of the Masterfile widely to "large pharmaceutical companies, hospitals, medical colleges and universities, medical equipment and supply companies, and commercial organizations."[7] The AMA has altered its Masterfile licensing agreement to require each pharmaceutical company licensee to withhold from its sales representatives and sales supervisors prescriber-identified data for all physicians who have elected to "opt out."

The Masterfile gives the AMA a means of strongly encouraging compliance with the PDRP. Physicians who participate in the program are informed that they may file complaints when they encounter practices that they believe violate the PDRP. When a complaint is filed, the AMA investigates, and if it discovers a violation, attempts to work with the violator to resolve the problem. If the violator fails to comply with the recommended resolution, or if it repeatedly violates PDRP rules, the AMA can revoke the violator's Masterfile license. This would be a serious consequence for any of the various licensees of the Masterfile.[8]

The PDRP is thus narrowly tailored to shield the prescriber-identified information of concerned physicians from only a discrete segment of the health care community:

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[7] Am. Med. Ass'n, AMA Database Licensing, http://www.ama-assn.org/ama/pub/category/print/2299.html (last visited Nov. 27, 2006).

[8] The Affidavit of Robert J. Hunkler, attached as an exhibit to the Complaint, also describes and endorses the benefits of the PDRP. *See* Hunkler Aff. ¶¶ 10–14.

pharmaceutical company sales representatives and their sales supervisors. The information remains available to other pharmaceutical company employees, including, for example, researchers looking for participants in clinical trials for new drug therapies. The PDRP also allows pharmaceutical companies to use prescriber-identified data to evaluate their marketing efforts and their employees' performance. This allows pharmaceutical companies to work more efficiently (and cost-effectively) by focusing their resources, including free samples, on the physicians (and patients) who will benefit the most.

The PDRP is narrowly tailored in a second sense—it covers only those prescribers who find the sharing of their prescribing practices offensive. Thus, sales representatives may continue to use prescriber-identified data to communicate with prescribers who do not choose to conceal their prescribing practices through the PDRP. This limited access to prescriber-identified data protects the interests of physicians who value the up-to-date information conveyed by pharmaceutical sales representatives,[9] as well as the interests of the patients who receive the benefit of such informed care. The AMA's experience in the first several months of the PDRP's operation suggests both that word has gotten out and that only a relatively small number of physicians wish to keep their prescribing practices from pharmaceutical sales representatives—as of September 2006, some 4,200 doctors have registered for the PDRP, a proportion equal to about one half of one percent of practicing physicians in the United States. *See* Warren Ross, *The Battle of New Hampshire*, Medical Marketing & Media, Nov. 2006, at 60, 61, *available at* http://www.mmm-online.com/content/fileadmin/files/features/2006/mmm_nov06_NH.pdf; Beth Herskovits, *IMS and Verispan Sue New Hampshire to Buy Prescriber Data—and to Protect the Data Sellers' Free-Speech Rights*, Pharmaceutical

[9] The Affidavit of Thomas P. Wharton Jr., M.D., F.A.C.C., attached as an exhibit to the Complaint, makes this point in some detail. *See* Wharton Aff. ¶¶ 12–16.

Executive, Sept. 1, 2006, http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=369271&pageID=3.

Overall, the PDRP balances the objections voiced by physicians to dissemination of information concerning their prescribing decisions, on the one hand, and the health care community's genuine need for accurate prescriber-identified data, on the other. The PDRP has the potential to realize the Prescription Restraint Law's objectives without also restraining speech that no physician even asks to have restrained.[10]

Significantly, pharmaceutical companies already have recognized physicians' concerns about their marketing practices and have taken significant steps to address those concerns. For example, on July 1, 2002, PhRMA, the leading association of pharmaceutical manufacturing companies, adopted the Code on Interactions with Healthcare Professionals, which establishes ethical standards for pharmaceutical company sales representatives.[11] The Code covers all aspects of the relationship between pharmaceutical sales representatives and physicians, not just the use of prescriber-identified data in sales pitches. It also strongly encourages pharmaceutical companies to develop internal guidelines to promote compliance with the Code.[12] The

[10] The PDRP is not the AMA's only voluntary effort to address physicians' concerns about pharmaceutical sales representatives. The AMA's "Do Not Release" policy, which has been in place for over twenty years, allows physicians to indicate that they do not wish their information to be included in the Masterfile at all. *See* Am. Med. Ass'n, *A Message From the AMA About Physician Data Distribution and Privacy*, http://www.ama-assn.org/ama1/pub/upload/mm/432/dblprivacy2006.pdf (last visited Nov. 27, 2006).

[11] PhRMA, *PhRMA Code on Interactions with Healthcare Professionals* 1 (2004), http://www.phrma.org/files/PhRMA%20Code.pdf.

[12] *Id.*

manufacturers of medical devices, who also field sales representatives, have followed suit and implemented a similar code.[13]

* * * * * *

New Hampshire's Prescription Restraint Law should be subject to the most searching constitutional scrutiny because it both prohibits truthful speech about matters of public concern and, through the use of broad and imprecise language, chills other extremely valuable speech—speech that serves the public interest in important ways. Even if the law is judged to be a regulation of commercial speech subject to intermediate scrutiny, it is plain that much narrower alternatives exist. The AMA's recently implemented Prescribing Data Restriction Program is one such alternative that will keep from pharmaceutical company sales employees the prescribing practices of those physicians who want their prescribing practices shielded without also imposing a direct restraint against the communication of vast quantities of valuable information.

[13] AvaMed, *Code of Ethics on Interactions with Health Care Professionals*, Sept. 3, 2003, http://www.advamed.org/publicdocs/code_of_ethics.pdf.

CONCLUSION

For the foregoing reasons, *Amicus Curiae* Wolters Kluwer Health respectfully requests that this Court rule in Plaintiffs' favor and invalidate the Prescription Restraint Law's restrictions on the use of prescriber-identified data as unconstitutional under the First and Fourteenth Amendments.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on this date the foregoing BRIEF OF *AMICUS CURIAE* WOLTERS KLUWER HEALTH, INC. IN SUPPORT OF PLAINTIFFS' POSITION was served via the ECF system on:

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